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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/520,130	03/07/2000	Robert Arathoon	12279-481-999	1353
20583	7590	09/15/2010		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER HOLLERAN, ANNE L	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/520,130	Applicant(s) ARATHOON ET AL.	
	Examiner ANNE L. HOLLERAN	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-70 and 73-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64-70 and 73-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/30/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed 6/30/2010 is acknowledged.

Claims 64-70 and 73-77 are pending and examined on the merits.

Claim Rejections Withdrawn:

The provisional rejection of claims 64-77 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 56-77 of copending Application No. 09/373,403 is withdrawn in view of the abandonment of application no. 09/373,403.

The rejection of claims 64-77 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment to the claims.

Claim Rejections Maintained and New Grounds of Rejection:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 64-70 and 73-77 remain/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 45-82 of US Patent No. 7,183,076. The rejection is maintained for the reasons of record.

Applicants have requested that the examiner hold these rejections in abeyance until notice of allowable subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 64, 65, 69, 70, and 76 remain rejected under 35 U.S.C. 102(b) as being anticipated by Tachibana (Tachibana, H., et al. Hum. Antibod. Hybridomas, 4: 42-46, 1993; cited in IDS) for the reasons of record.

Applicants state that Tachibana does not expressly disclose the heterologous association of a first heavy chain polypeptide and a second heavy chain polypeptide, which first and second heavy chain polypeptides each combine with a common light chain to bind two different antigens as recited in the instant claims.

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The examiner does not agree with applicants' statement because Tachibana teaches antibodies that bind to two different antigens (Cpase and ds DNA), that the antibodies are hybrid antibodies that have Mu chain from each of the individual antibodies (anti-Cpase Mu and anti-ds DNA Mu; see Table 1, for example hybrid antibodies A9C11, A9H6 and A9F6). The clones that produce these antibodies result from limiting dilution (see page 43, right column). Therefore, these clones produce a single species of heterologous antibody. Tachibana teaches that the anti-Cpase antibodies from the hybrid hybridomas were hybrid antibodies generated by heterologous association of heavy chain derived from 6T-C5 and lambda light chain derived from 5B-SU. Since the anti-ds DNA antibody also contains an association of the lambda light chain from 5B-SU with the anti-ds DNA heavy chain (5B-SU heavy chain), the hybrid hybridomas of Tachibana contain IgM antibodies that bind to both Cpase and ds DNA, where the antibodies comprise a set of at least two light chains that are identical. Putting this into the words used in the claims, the Mu chain from 5B-SU is the first polypeptide (heavy chain, comprising a heavy chain constant domain and a heavy chain variable domain), the Mu chain from 6T-C5 is the second polypeptide (heavy chain, comprising heavy chain constant domain and a heavy chain variable domain), and the lambda chain from the lambda chain from 5B-SU is the third and fourth polypeptides, common light chains that are identical to each other. Therefore, there is explicit teaching of the limitations of the rejected claims.

Applicants state that Tachibana fails to inherently teach the claimed inventions because Tachibana teaches IgM antibodies that are pentameric, and it is possible that each "Y" subunit of the pentameric IgM will contain two Mu chains that are identical. Even if, as applicant theorizes, that the two different Mu chains are contained within two different "Y" units of the

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pentameric molecule, the Mu chains are dimerized and form a multispecific antibody that happens to be a pentameric structure. Therefore, the claims do not exclude the IgM structures of Tachibana.

Thus, the rejection is maintained for the reasons of record.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If

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attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643